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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96 N-0393]

Agency Information Collection Activities; Proposed Collection; MedWatch: The FDA Medical Products Reporting Program; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed revision of two forms for collection of certain information by the agency, Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response [o the notice. This notice solicits comments on the proposed revision of two forms from " MedWatch: The FDA Medical Products Reporting Program" (MedWatch). These forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), will be used to report to the agency on adverse events and product problems that occur with all medical products regulated by FDA.

DATES: Submit written comments on the collection of information by (*insert date* 60 days *after date of publication in the* Federal Register).

ADDRESSES: Submit written requests for single copies of the revised MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), and a summary of the proposed revisions to the forms, by e-mail to ''medwatch@oc.fda.gov'', by fax to 301–827–7241, or by mail to ' 'MedWatch: The FDA Medical Product Reporting Program, " Food and Drug Administration (HF–2), 5600 Fishers Lane, rm. 17-65, Rockville, MD 20857 (301-827-7240). Requests by mail should include one self-addressed adhesive label to assist that office in processing

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your request. Copies of the forms and the summary of the changes may also be obtained via Internet at ''http://www.fda.gov/medwatch'' under ''How to Report''.

Submit written comments on the revised MedWatch reporting forms [o the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. " 'Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information

on respondents. including through the use of automated collection techniques, when appropriate. and other forms of information technology.

MedWatch—The FDA Medical Products Reporting Program (Forms FDA **3500** and FDA **3500A**) (OMB Control Number 0910–0291—Revision)

Under sections 505, 507, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 357, 360b, 360c, 360e, and 393); and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act it is misbranded if it fails to bear adequate warnings, and under section **502(j),** it is misbranded if it is dangerous to health when used as directed in its labeling.

Under section 4 of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) (21 U.S.C. 301), section 402 of the act (21 U. SC. 342) is amended so that FDA must bear the burden of proof to show a dietary supplement is unsafe.

To carry out its responsibilities, the agency needs to be informed whenever an adverse event or product problem occurs. Only if FDA is provided with such information, will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce or eliminate the public's exposure to the risk through regulatory action ranging from labeling changes to the rare product withdrawal. To ensure the marketing of safe and effective products, certain adverse events must be reported. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR 310, 314,600, and 803), specifically $$310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, and 803.56.

To implement these provisions for reporting of adverse events and product problems with all medications, devices, and biologics, as well as any other products that are regulated by FDA, two very similar forms are used. Form FDA 3500 is used for voluntary (i.e., not mandated by

law or regulation) reporting of adverse events and product problems by health professionals and the public. Form FDA 3500A is used for mandatory reporting (i.e., required by law or regulation). Respondents to this collection of information are health professionals, hospitals and other user-facilities (e.g., nursing homes, etc.), consumers, manufacturers of biologics, drugs and medical devices, distributors, and importers.

II. Use of the Voluntary Version (FDA Form 3500):

Individual health professionals are not required by law or regulation to submit adverse event or product problem reports to the agency or the manufacturer. There is one exception. The National Childhood Injury Act of 1986 mandates that certain adverse reactions following immunization be reported by physicians to the joint FDA/Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS).

Hospitals are not required by Federal law or regulation to submit adverse event reports on medications. However, hospitals and other medical facilities are required by Federal law to report medical device related deaths and serious injuries.

Manufacturers of dietary supplements do not have to prove safety or efficacy of their products prior to marketing, nor do they have mandatory requirements for reporting adverse reactions to FDA. However, the DSHEA of 1994 puts the onus on FDA to prove that a particular product is unsafe. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements.

The voluntary version of the form is used to submit all adverse event and product problem reports not mandated by Federal law or regulation.

Experience over the past 5 years has revealed the need to modify the voluntary form to better utilize the available space and to better query reporters for information specific to dietary supplements and medication quality problems.

111. Use of the Mandator-y Version (FDA Form 35004):

A. Drug and Biologic Products

In section 505(j) and 704 (21U.S.C.374) of the act, Congress has required that important safety information relating to all human prescription drug products be made available [o FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and part 600 (biologics) of the Code of Federal Regulations. Parts 310, 314, and 600 mandate the use of the FDA Form 3500A for reporting to FDA on adverse events that occur with drugs and biologics.

B. Medical Device Products

Section 519 of the act (21U.S.C.360i) requires manufacturers, importers, or distributors of devices intended for human use [o establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to ensure that such devices are not adulterated or misbranded and to otherwise ensure its safety and effectiveness. Furthermore. the Safe Medical Device Act of 1990, signed into law on November 28,1990, amends section 519 of the act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 CFR part 803 (part 803). Part 803 mandates the use of FDA Form 3500A for reporting to FDA on medical devices.

C. Other Products Used in Medical Therapy

There are no mandatory requirements for the reporting of adverse events or product problems with products such as dietary supplements. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements.

The mandatory form has been modified to incorporate some new data elements and to allow drug and biologic manufacturers to use only the front page rather than the full two-page form. (Note: Most pharmaceutical manufacturers already use a one-page modified version of [he 3500A form where Section G from the back of the form is substituted for Section D on the front of the form.)

IV. Estimated Reporting Burden

FDA estimates the burden for completing the forms for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center(s)[1] and Forms (with applicable 21 CFR Section)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER					
Form 3500[2]	16,008	1	16,008	0.5	8,004
Form 3500A[3] (§§ 310.305, 314.80, 314.98, and 600.80)	410	573.9	235,304	1.0	235,304
CDRH					
Form 3500[2]	2,353	1	2,353	0.5	1,176,5
Form 3500A[3] (§ 803)	3.116	24.8	77,337	1.0	77,337
CFSAN					
Form 3500[2]	237	1	237	0.5	118.5
Form 3500A[3] (no mandatory requirements)	0	0	0	1.0	0
Total Hours					321,940
Form 3500[2]					9,299
Form 3500A[3]					312,641

[1] CBER (Center for Biologics Evaluation and Research), CDER (Center for Drug Evaluation and Research), CDRH (Center for Devices and Radiological Health), and CFSAN (Center for Food Safety and Applied Nutrition).
[2] FDA Form 3500 is for voluntary reporting.
[3] FDA Form 3500A is for mandatory reporting.

The figures shown in Table 1 of this document are based on actual number of calendar year 1997 reports and respondents for each center and type of report.

As more medical products are approved by FDA and marketed, and as knowledge increases regarding the importance of notifying FDA when adverse events and product problems are observed, it is expected that more reports will be submitted.

V. Request for Comments

Interested persons may, on or before (*insert date 60 days after date of publication in the* Federal Register), submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading

of this document. Received comments and copies of the revised MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), may be seen in the office above between 9 a.m. and -1 p.m., Monday through Friday.

Dated: October 30, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Dec. 98–????Filed '? '.'-'? '?-9S: 8:45am]

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October 30, 1998

U.S. Food and Drug Administration

MEDWATCH

The FDA Medical Products Reporting Program

Proposed Revisions to Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory)

USE OF AND CHANGES TO THE VOLUNTARY VERSION (FDA Form 3500):

Individual health professionals are not required by law or regulation to submit adverse event or product problem reports to the Agency or the manufacturer. There is one exception. The National Childhood Injury Act of 1986 mandates that certain adverse reactions following immunization be reported by physicians to the joint FDA/CDC Vaccine Adverse Event Reporting System (VAERS).

Hospitals are not required by law or regulation to submit adverse event reports on medications. However, hospitals and other medical facilities are required by federal law to report medical device related deaths and serious injuries.

Manufacturers of dietary supplements do not have to prove safety or efficacy of their products prior to marketing, nor do they have mandatory requirements for reporting adverse reactions to FDA. However, the Federal Dietary Supplement Health and Education Act (DSHEA) of 1994 puts the onus on FDA to prove that a particular product is unsafe. Consequently, the Agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements.

The voluntary version of the form is used to submit all adverse event and product problem reports not mandated by federal law or regulation.

Experience over the past 5 years has revealed the need to modify the voluntary form to better utilize the available space and to better query reporters for information specific to dietary supplements and medication quality problems.

The changes to the front of the 3500 areas follows:

SECTION A: Patient information

A5 “Height” - new addition (To aid in the assessment of weight information obtained in A4)

SECTION B: Adverse event and/or product problem

B1 "Adverse event and/or Product problem" - check boxes moved to within header for Section B, with additional notation to "(see back)" (To make distinction more prominent to reporter)

B2 "Outcomes attributed to adverse event" - Title changed to "If adverse event, patient outcome", with "other" box - deleted and replaced with "none of the above (explain in B3)" (To obtain further clarifying information on a report that does not fit specific criteria for a serious adverse event)

B3 "Describe event or problem" - former B5

B4 "Date of event" - former B3

Former B4 "Date of this report" - moved to Section D as D3

B5 "Relevant tests/laboratory data" - former B6

B6 "Other relevant history, including preexisting medical conditions" - former B7, with "race" moved to first in list of specified examples of data requested (To encourage reporting of information to aid in the identification of subpopulations at possible increased risk - race categories listed in the complete instructions to the form)

B7 "Concurrent medical products" - former C 10 & D1 O combined together and moved to Section B (To allow for more efficient use of limited space)

SECTION C: Suspect products(s)

Former Section C "Suspect medication(s)" and former Section D "Suspect medical device" sections combined into new Section C - "Suspect product(s)", with additional direction to "(fill in those sections that apply)" (To allow for more efficient use of limited space, and to encourage more complete reporting)

Throughout Section C, in those data elements that have lines to be utilized for completion, the enumeration has been changed from numbers (#1 and #2) to letters (a and b)

Cl "Brand name (include strength and dosage form)" - data block title changed from "Name (give labeled strength & mfr/labeler, if known)" (To facilitate accurate reporting of requested information)

C2 "Generic name (or ingredients) or type of device" - both new addition and moving of former element ("Type of device" from former D2) (To facilitate increased and accurate reporting of requested information)

C3 "Dose, frequency& route used" - former C2

C4 "Therapy dates (or implant/explant dates)" - combines former C3 "Therapy dates (if unknown, give duration)", former D7 "If implanted, give date", and former D8 "If explanted, give date". (To allow for more efficient use of limited space)

C5 "Diagnosis for use (indication)" - former C4

C6 "Exp. Date" - former C7

C7 "Product is Rx/OTC" - new addition (Element has always been on the mandatory form - 3500A, block G5 - but not on the voluntary. Added to aid in the identification of the actual product.)

C8 "Event abated after use stopped or dose reduced?" - former C5, with addition of an "unknown" box

C9 "Event reappeared after reintroduction?" - former C8

C1O "Use of device (initial, reuse, unknown)" - new addition (Element has always been on the mandatory form -3 500A, block H8 - but not on the voluntary form. Added to provide more information on how the device was actually used)

Cll "Product #(s)" - combines former C6 ("Lot #"), C9 ("NDC #"), and D6

C12 "If device, operator is" replaces former D4 "Operator of device"

C13 "Product available for evaluation" - replaces former D9 "Device available for evaluation" (To encourage reporters to provide more information on product problems and dietary supplements)

C14 "Label available?" - new addition (Specific to product problems and dietary supplements, added to provide more information on the product)

C15 "Manufacturer name and address" - former D3 "Manufacturer name and address" (Block can now be used to provide names and addresses for the manufacturer of any product.)

C16 "Directions for use" - new addition (To provide more information on dietary supplements)

SECTION D: Reporter (formerly Section E)

D1 & D2 "Name, address" &"Phone number" - former El

D3 "Date of this report" - former B3

D4 "Health professional" - former E2

D5 "Occupation/specialty" - former E3 "Occupation" (To collect more data on health professional specialty)

D6 "Attachments included?" - new addition (Added as signal to data entry staff to look for attachments)

D7 "Follow-up report? FDA ref # (if known)" - new addition (Added as signal to data entry staff to link the follow-up report to the original report)

D8 "Also reported to" - former E4

D9 "If you do NOT want your identity disclosed to the manufacturer, place an 'X' in this box" - former E5

The changes to the back of the 3500 areas follows: Modifications to the text.

USE OF AND CHANGES TO THE MANDATORY VERSION (FDA Form 3500A):

Drug and biologic products -

In sections 505(j) and 704 (21 U.S.C. 374) of the FD&C Act, Congress has required that important safety information relating to all human prescription drug products be made available to the FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the Federal Food, Drug, and Cosmetic Act authorizes investigational powers to the FDA for enforcement of the FD&C Act. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 sections310&314 (drugs) and 600 (biologics) of the Code of Federal Regulations. 21 CFR sections 310,314, and 600 mandate the use of the FDA Form 3500A form for reporting to FDA on adverse events that occur with drug and biologics.

Medical device products -

Section 519 of the FD&C Act requires manufacturers, importers, or distributors of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. Furthermore, the Safe Medical Device Act (SMDA) of 1990, signed into law on November 28, 1990, amends Section519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 section 803 of the Code of Federal Regulations. 21 section 803 mandates the use of the FDA Form 3500A for reporting to FDA on medical devices.

Other products used in medical therapy -

There are no mandatory requirements for the reporting of adverse events or product problems with products such as dietary supplements. However, the Federal Dietary Supplement Health and Education Act (DSHEA) of 1994 puts the onus on FDA to prove that a particular product is unsafe.

The mandatory form has been modified to incorporate some new data elements and to allow drug and biologic manufacturers to use only the front page rather than the full two-page form. [Note: Most pharmaceutical manufacturers already use a one-page modified version of the 3500A form where Section G from the back of the form is substituted for Section D on the front of the form.]

The changes to the front of the 3500A areas follows:

SECTION A: Patient information

A3 “Sex” - check box for “unknown” added

A5 “Height” - new addition (To aid in the assessment of weight information obtained in A4)

SECTION B: Adverse event and/or product problem

B1 “Adverse event and/or Product problem” - check boxes moved to within header for Section B (To make distinction more prominent to reporter)

132 “Outcomes attributed to adverse event” - now titled “If adverse event, patient outcome”, with “other” box replaced by “unknown”, “required intervention to prevent permanent impairment and damage” box shortened to “required intervention”, and “non-serious” box added (To further specify classification for adverse event, so as to facilitate form completion, and indicate that the manufacturer has made a determination that the report is not a report on a serious event).)

B3 “Describe event or problem” - former B5

B4 “Date of event” - former B3

Former B4 “Date of this report” - moved to Section D as D3 and retitled “Date report completed”

B5 “Relevant tests/laboratory data” - former B6

B6 “Other relevant history, including preexisting medical conditions” - former B7, with “race” moved to first in list of specified examples of data requested (To encourage reporting of information to aid in the identification of subpopulations at possible increased risk - race categories listed in complete guidance to use of form)

B7 “Concurrent medical products” - former C 10 & D1O combined together and moved to Section B (To allow for more efficient use of limited space)

SECTION C: Suspect medication(s)

Throughout Section C, in those data elements that have lines to be utilized for completion, the enumeration has been changed from numbers (#1 and #2) to letters (a and b)

Cl “Name (include strength and dosage form)” - data block title changed from “Name (give labeled strength & mfr/labeler, if known)” (To facilitate accurate reporting of requested information)

C4 “Indication for use” - retitled from “Diagnosis for use (indication)”

C5 “Event abated after use stopped or dose reduced?” - addition of an “unknown” box

C6 “Event reappeared after reintroduction?” - former C8

C7 “Lot #“ - former C6

C8 “Expiration Date” - former C7 "Exp. date”

Former C9 “NDC #“ deleted (not necessary for reporting adverse events)

Former C1O “Concomitant medical products” moved to Section B as B7

SECTION D: Initial Reporter (formerly Section E)

D1 & D2 “Name, address” &“Phone number” - former El

D3 “Date report completed” - moved from Section B and retitled. (To clarify that the date

requested is the date the initial reporter completes the report)

D4 “Health professional” former E2

D5 "Attachments included?” - new addition (Added as signal to data entry staff to look for attachments)

D6 “Initial reporter also sent voluntary report to FDA” - former E4 with the word “voluntary” added

D7 “Occupation/specialty” - former E3 “Occupation” (To collect more data on health professional specialty)

SECTION E: All manufacturers (formerly Section G on back of form)

El “Contact office - name, address” - former G1

E2 “Phone number” - former G2

E3 “Report source” - former G3 with “importer” box added (To reflect current medical device regulations)

E4 “Date received by mfr” - former G4

E5 “PLA #“ changed to “BLA #“ (To reflect name change)

E6 “Date report submitted to FDA”- new addition (To reflect date actually sent to FDA

E7 "If IND, protocol #“ - former G6

E8 “Type of report” - former G7 - “10-day” deleted; “7-day” and “baseline” added; and FDA ref # added (To reflect current regulations, and to signal the data entry staff to link to the original report)

E9 “Adverse event term(s)” - Former G8

Former G9 “Mfr. report number” - deleted (found on upper right corner of front page)

The changes to the back of the 3500A areas follows:

SECTION F: Suspect Device (formerly Section D “Suspect Medical Device” on front of form with the addition of some elements from former Sections F & H)

F1 “Manufacturer name, address” - former D3

F2 “Brand name” - former D1 with “unknown” box added and a shaded area for manufacturer use only added

F3 “Type of device” - former D2 and D6 with a new “unknown” box incorporated, and a shaded area for manufacturer use only added

F4 “Expiration date” - former D5

F5 “If implanted, give date” - former D7

F6 “If explanted, give date” - former D8

F7 “Approximate age of device” - former F9

F8 “Device available for evaluation?” - former D9

F9 “Operator of device” - former D4

F1O “Usage of device” - former H8

SECTION G: Additional event information/codes - devices (new section with some elements moved from former Section F)

G1 “Location where event occurred” - former F 12

G2 “Event problem codes” - former F 10, with a shaded area for manufacturer use only denoting whether codes are labeled or not

SECTION H: User facility/importer - devices (formerly Section F “For use by user facility/distributor - devices only”) (“Distributor” changed to “Importer” throughout section to reflect change in regulations)

H1 “User facility or importer name/address” - former F3 with “user facility” and “importer” boxes added

H2 “Contact person” - former F4

Former F2 "UF/Dist report number” - moved to upper right corner

H3 “Phone number” - former F5

H4 “Type of report” - former F7

Former F8 “Date of this report” - moved to upper right corner

H5 “Date user facility/importer became aware of event” - former F6

H6 “Report sent to manufacturer?” - former F 13

H7 “Report sent to FDA?” - former F 11

Former F9 “Approximate age of device” - moved to Section F as F7

Former F1O “Event problem codes” - moved to Section Gas G2

Former F12 “Location where event occurred” - moved to Section Gas G1

Former F14 “Manufacturer name/address” - deleted, can be found in Section F

SECTION I: Device manufacturers only (formerly Section H)

11 “Type of reportable event” - former H1, with “malfunction (see guidelines)” replaced by "malfunction" and “other” replaced by “other significant adverse event”

12 “If follow-up, what type” - former H2

13 “Device manufacture date” - former H4

14 “Labeled for single use?” - former H5

15 “Device evaluated by manufacturer?” - former H3 “Device evaluated by mfr?" with two boxes (“yes” and “no, provide code”) replacing previous options

16 “If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number” - former H9

17 “Evaluation codes” - former H6, with letters added for all 3 categories

I8 “Remedial action initiated” - former H7 “If remedial action initiated, check type” -, with “yes” and “no” boxes, and “Type” replacing previous options

Former H8 “Usage of device” - moved to Section F as F 10

19 “Additional manufacturer narrative” - former H1O

110 “Corrected data” - former H11

SECTION J: Baseline information - devices (new section - pursuant to Paperwork Reduction Act review that suggested combining the Baseline Report and the MedWatch form to eliminate duplicative collection of information.)

In header, “initial” and “update” boxes

J2 “FDA product code”

J3 “Device manufactured at other sites?”

J4 “Manufacturer’s device family name”

J5 “Related device identification”

J6 “Device life”

J7 “Date device first marketed”

J8 “ Date device ceased being marketed (if applicable)”

J9 “Basis for marketing”

J1O “Device reporting site registration number and street address”

MEDWATCH